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June 21, 2001

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

Re: U.S. Utility Patent Application

App. No: 09/662,478 Filed: September 15, 2000

For: DNA Encoding von Willebrand Factor and Methods of Use

Inventors: Venta, P.J. et al.

Ref. No.: UMV-1226CPPCUS

Dear Sir:

The following documents are forwarded herewith for appropriate action by the U.S. Patent and Trademark Office:

1. Protest under 37 CFR 1.291(a);
2. Copy of summary judgment motion and attached exhibits;
3. Proof of service on Patent Owner; and
4. Postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier.

Respectfully submitted,

SHANKS & HERBERT


Joseph G. Connera
11/2/00

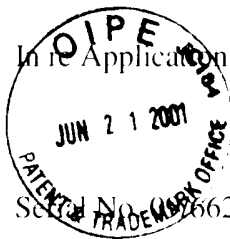
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JUN 25 2001

TECH CENTER 1600 2900

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Venta, P.J. et al.



Serial No. 09/662,478

Art Unit: 1652

Examiner: (unknown)

Filed: 9/15/2000

Atty. Docket: UMV-1226CPPCUS

For: DNA Encoding von Willebrand Factor and
Methods of Use

ATTENTION: PROTEST UNDER 37 CFR 1.291(a)

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

Sir:

I. Identification Of Patent Application For Which Relevant Documents Are Being Submitted in Protest

GeneSearch, L.L.C. respectfully submits the instant protest under 37 C.F.R. § 1.291(a) against the patentability of claims 30-45 of U.S. Patent Application serial number 09/662,478 ("the '478 application") filed September 15, 2000, and assigned to The Regents of The University of Michigan and The Board of Trustees of Michigan State University ("the Patent Owners"). The '478 application claims priority to PCT patent application serial number PCT/US99/18153, filed August 10, 1999, which claims priority to U.S. Patent No. 6,074,832 ("the '832 patent") issued June 13, 2000.

II. Discussion of the Prior Art and the Patentability of the Claims

The '832 patent from which the '478 application is derived, is currently involved in a litigation proceeding pending in the Eastern District Court of Michigan, Southern District of Michigan, and the U.S. District Court for the District of Columbia. The litigation involves the validity of the '832 patent and the '478 application.

L.L.C. ("VetGen") against GeneSearch L.L.C. and Dr. Mary H. Whiteley ("the Protestors")(Case No. 5:00-CV-60250). In the course of the above litigation, the Protestors have filed a motion for summary judgment with the Court, arguing that the claims of the '832 patent are invalid under 35 U.S.C. § 102(b) because the inventions disclosed and claimed in the '832 patent were offered for sale and sold more than one year prior to the filing date of the application which matured into the '832 patent, and are ineligible for patenting under the on-sale bar.

III. References Warranting Protest

Included with this protest is Defendants' summary judgment motion for invalidity of the '832 patent and attached exhibits. The references directly relevant to this protest are attached as exhibits to the Protestors motion and are identified as follows:

- 1) U.S. Patent 6,074,832;
- 2) An internal memo detailing VetGen's marketing activities with respect to the Doberman and Sheltie vWD tests dated October 24, 1996. (Exhibit H, V01853-4);
- 3) Customer records collected by GeneSearch show that VetGen began selling the test for vWD in Shetland Sheepdogs at least as early November of 1996 (21 months prior to filing the '832 patent). (Exhibit L);
- 4) Quarterly royalty reports from exclusive licensee VetGen, L.L.C. to the University of Michigan for net revenue based on sales of vWD tests in Scottish Terriers, Doberman Pinschers, and Shetland Sheepdogs. For the period ending December 31, 1996, VetGen identified net revenue from sales of Shetland Sheepdog vWD tests of \$540.00. VetGen then paid a 5% royalty to Michigan based on total net revenue. (Exhibit O, V01007);

Doberman Pinschers, and Shetland Sheepdogs for the period of January 1 to March 31, 1997, VetGen identified net revenue from sales of Shetland Sheepdog vWD tests of

\$4,986.00. VetGen then paid a 5% royalty to Michigan based on total net revenue. (Exhibit P, V00998);

6) The Orthopedic Foundation for Animals ("OFA") is a not-for-profit is a not-for-profit organization originally created to assist breeders in addressing hip dysplasia. In recent years OFA has added databases to assist breeders in assessing elbow and patella deformities, craniomandibular osteopathy, autoimmune thyroiditis, congenital heart disease, copper toxicosis in Bedlington Terriers, and DNA databases. OFA currently supports canine genetic research at the University of Michigan, Michigan State University and the University of Missouri. Advertising from OFA informational materials indicates that OFA supplied a list VetGen's available genetic tests when DNA registry information was requested from OFA by the public. A copy of VetGen's January 1997 advertising flyer identifies vWD tests for Scotties, Shelties, Dobermans, and Manchester Terriers (19 months prior to filing the '832 patent). (Exhibit S);

7) Royalty reports indicating total net revenue based on sales of vWD tests from April 1997 until December 1997 was \$15,454 for Shelties (16 months prior to filing the '832 patent). (Exhibit T, V00979, V00985-6);

8) U.S. Patent 6,040,143 issued March 21, 2000; and

9) The March 1997 AKC Gazette, pp.34-35. On page 35 of the exhibit, the article clearly states, *inter alia*, that the Shetland Sheepdog test for vWD is available from VetGen and its cost of \$135 (17 months prior to filing the '832 patent) (Exhibit Z).

IV. Substantial Issue of Patentability Raised by the References

A. Claims 30-45 of The '478 Application Can Only Claim Priority to the Filing Date of the '832 Patent of August 11, 1998

factor gene that caused Type I vWD in Doberman Pinschers, Manchester Terriers, and Poodles. The '832 patent also disclosed and claimed a different mutation in the canine

von Willebrand's factor gene that allegedly causes Type III vWD in Shetland Sheepdogs ("Shelties"). Those claims to the Sheltie mutation were restricted out of the '832 patent.

The Patent Owners had filed an earlier parent U.S. Patent application 08/896,449 on July 18, 1997 and claimed priority to a provisional U.S. Patent application 60/020,998 filed July 19, 1996. The '449 application matured into U.S. Patent 6,040,143, and discloses and claims a mutation in the canine von Willebrand's factor gene that allegedly causes Type III vWD in Scottish Terriers (Exhibit V). The mutation that causes Type III vWD in Scottish Terriers is different than the mutation that causes Type III vWD in Shelties.

The Patent Owners then filed U.S. Patent application 09/132,652, which was designated a continuation-in-part application of the earlier '449 application. The '652 application contained the identical information in the specification that was disclosed in the '449 application. That is, the new '652 application identified the same information about cDNA sequence that allegedly encoded a vWF gene in Scottish Terriers and identified the deletion mutation, which causes Type III vWD in Scotties as in the '449 application. In addition to that information, the '652 application also contained new information (new matter), which allegedly identified the mutation that causes Type I vWD in Dobermans, Poodles, and Manchester Terriers, and identified another mutation that allegedly causes Type III vWD in Shelties (Exhibit B). The new matter in the '652 application comprised specific examples 2 through 5 of the text of the specification, figures 6 through 12, claims 1 through 17, and SEQ. ID Nos. 12-29 (Exhibit B).

Because the '652 application as filed also taught and claimed the Sheltie Type III mutation (now pending as claims 30-45 of the '478 application), the claims to the Sheltie Type III mutation were also new matter at the time the '652 application was filed, and therefore, claims 30-45 of the '478 application cannot claim priority to the earliest effective filing date of the '143 patent (July 19, 1996), but can only claim the earliest

B. VetGen's Commercial Sales Activities for the Shetland Sheepdog Test Make Claims 30-45 of the '478 Application Ineligible for Patenting Under the On-Sale bar of 35 U.S.C. § 102(b)

The Protestors moved the Court in the above case for partial summary judgment that United States Letters Patent No. 6,074,832 ("the '832 patent"), co-owned by The Regents of the University of Michigan ("Michigan") and The Board of Trustees of Michigan State University ("MSU"), is invalid under 35 U.S.C. § 102(b). GeneSearch's motion was based on the fact that VetGen, either by itself or in conjunction with the Patent Owners, continuously advertised, offered for sale, or sold Type I and Type III canine von Willebrand's Disease ("vWD") tests to members of the public more than one year before the filing date of the patent application that matured into the '832 patent.

Exhibit A of Protestors' motion shows a timeline identifying where each sales related activity by VetGen (identified by Exhibit) occurred before the filing date of the '832 patent. (Exhibit A) The repeated offers for sale and sales of the tests for Type I vWD in Doberman Pinschers, Manchester Terriers, and Poodles more than a year prior to the filing of the application claiming these tests thereby renders the claims of the '832 patent invalid and unenforceable under the "on-sale" provision of 35 U.S.C. § 102(b).

The references identified by the Protestors in section III above, and discussed in Protestors' motion, also show that the Patent Owners offered for sale and sold the *Shetland Sheepdog* vWD test more than one year before the earliest effective filing date of August 11, 1998. Reference No. 2 indicates that the Patent Owners were already marketing the test in October 1996. Reference No. 3 shows an actual test report for a *Shetland Sheepdog* vWD test for a customer dated November of 1996, 21 months before the filing date of '832 patent. Reference Nos. 4-5, and 7 show royalty reports from the

Nos. 6 and 9 show that the *Shetland Sheepdog* vWD test was advertised publicly for sale at least 17 months prior to the filing date of the '832 patent.


The above references clearly show that the Patent Owners and their Licensee offered for sale and sold the Type III test for vWD in Shelties more than one year before the earliest effective filing date of August 11, 1998, and therefore the inventions of claims 30-45 of the '478 application should be barred from patentability under 35 U.S.C. § 102(b).

VI. Conclusion

Accordingly for the reasons given above, the U.S.P.T.O. should reject claims 30-45 of the '478 application, and any related claims regarding the Sheltie Type III mutation under 35 U.S.C. § 102(b) for being on-sale more than one year prior to their earliest effective filing date of August 11, 1998.

Respectfully submitted,

SHANKS & HERBERT



Joseph G. Contrera
Reg. No. 44,628

Date: 6/11/98

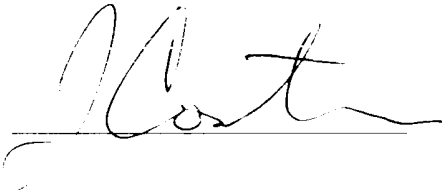
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Certificate of Service

The undersigned certifies that a copy of this paper is being served this 21st day of June 2001, via first-class mail, postage prepaid, on the Patent Owner at the following address:

George T. Schooff, Esq.
Harness, Dickey & Pierce, P.L.C.
5445 Corporate Drive
Troy, MI 48098
Attorney for Plaintiff/Counter-Defendant

Signed: _____

A handwritten signature in black ink, appearing to read "G. Schooff", is written over a horizontal line. The signature is fluid and cursive.